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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/610,949	07/01/2003	Samuel J. Gason	58450US002	4108

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/610,949	GASON ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-34 and 37-44* is/are allowed.

6)☒ Claim(s) *35,36 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/29/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 35 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bedingham et al. (US 6,662,830 B1) ("Bedingham I").

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Bedingham I discloses a device for processing sample material, the device comprising a substrate (10) comprising first and second major surfaces and a hub defining a central axis of rotation for the substrate (abstract and Figure 1); a channel (50), the channel adapted to fractionate a sample material (col. 14:44-61). Although Bedingham I does not mention whether the channel is unvented having the channel be unvented is implicitly disclosed by Bedingham because Bedingham discloses that the channel is *preferably* (not necessarily) vented and furthermore that need for venting deceases as the length of the electrophoresis channel decreases. See col. 9:9-13.

3. Claim 36 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bedingham et al. (US 6,987,253 B2) ("Bedingham II").

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Bedingham II discloses a device comprising

a substrate (810) comprising first and second major surfaces and a hub (812) defining a central axis of rotation for the substrate (abstract and Figure 18);

a channel (860) having an inner radius and outer radius, the channel comprising a plurality of connected compartments (850a, 850b,880); and a plurality of compartment connection structures (862) in contact with the radius of the channel.

4. Claim 45 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by the JPO English language computer translation of Arai (JP 08233778 A) ("Arai").

Arai discloses a device for processing sample material, the device comprising

a substrate (51) comprising first and second major surfaces (Drawings 5(a)-(c)) and at least one channel (55);

a sample well for holding a fluid (53), said well connected to the channel (Drawing 5c);

an integrated electrode (27) configured to make contact with the fluid when present in the device (Drawings 1 and 2); and

a contact point (15) outside of the well that permits delivery of an electric current to the electrode (Drawing 3 and paragraph [0014] of the Detailed Description).

Claim Objections

5. Claims 5 and 32 are objected to because of the following informalities:

a) Claim 5: -- has -- should be inserted between "and" and "a" in line 1; and

b) Claim 32: in line 2 "modified is" should be deleted.

6. Appropriate correction is required.

Allowable Subject Matter

7. Claims 1-34 and 37-44 are allowed.

8. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 1: the combination of limitations is not taught by the prior art.

Bedingham et al. (US 6,987,253 B2) ("Bedingham") discloses a device for processing sample material, the device comprising a substrate comprising first and second major surfaces and a hub defining a central axis of rotation for the substrate; an

unvented channel (62, 662a, 66b, 860) having an inner radius and outer radius; and at least one compartment connection structure (60,660a, 862) in contact with the outer radius of the unvented channel. See the abstract; Figure 1; col. 12:43 – col. 13:20; col. 32:14-21 (vent is optional). However, in Bedingham the channel is not adapted to fractionate a sample material. It would not have been obvious to adapt the channel to fractionate a sample material because the channel functions as a loading channel for loading portions of the sample to the process chambers. See col. 12:43-46; col. 27:5-26; and col. 30:31-36. Bedingham implies leaving the sample in its original state while it is in the unvented channel (loading chamber) because filter chambers or filtering regions are provided in the channels branching off the unvented channel. See col. 27:19-22 and col. 29:15-14. The loading chamber may, in fact, be used to dispense filtering material to the branch channels. See col. 27:56 – col. 28:5.

Mayer et al. (US 6,610,186 B1) discloses a device for processing sample material, the device comprising a substrate comprising first and second major surfaces and a hub defining a central axis of rotation for the substrate ("hub" is broadly interpreted as "the central part of a circular object" – Merriam-Webster's Collegiate Dictionary, 10th edition, 1998); a channel (1) having an inner radius and outer radius, the channel adapted to fractionate a sample material; and at least one compartment connection structure (23) in contact with the outer radius of the channel. See the abstract and Figure 3. However the channel is vented. See col. 6:20-23. Channel 23 in Figure 3 of Mayer et al., which may be unvented (since it can be pressurized across

its ends), can not be construed as the claimed unvented channel because it does not have an inner radius and outer radius. See Figure 3 and col. 7:48-62.

Kopf-Sill et al. (US 5,160,702) discloses a device for processing sample material, the device comprising a substrate comprising first and second major surfaces and a hub defining a central axis of rotation for the substrate (abstract and Figure 1); a channel (36) having an inner radius and outer radius, the channel for fractioning a sample material (col. 5:44-46); and at least one compartment connection structure (42 or 34) in contact with outer radius of the channel (Figure 1). However, although the channel is used for fractionating sample, it is not clear that is adapted to fractionate a sample material as intended by Applicant, such as by forming a pH gradient in the channel. Also, the channel is not unvented as defined by Applicant (page 6 of the specification) as there is an air vent adjacent the junction of compartment connection structure 42 and the channel (col. 5:62-64) and indeed in the channel itself (col. 4:36-39). Additionally, neither compartment connection structure (42 or 34) is in contact with the outer radius of the channel, but instead they contact the inner radius of the channel.

Bedingham et al. (US 6,662,830 B2) discloses a device for processing sample material, the device comprising a substrate comprising first and second major surfaces and a hub defining a central axis of rotation for the substrate (abstract and Figure 1); an unvented channel (250 – Figure 7), the channel adapted to fractionate a sample material (col. 14:44-61). However, the channel does not have an inner radius and an outer radius as they are not curved in an arc (col. 14:35-42). Also, there is not at least one compartment connection structure in contact with the outer radius of the unvented

channel. Each end of the channel directly contacts a compartment (270, 220d). In the embodiment of Figure 1 there is a channel (50) having an inner radius and outer radius, the channel being adapted to fractionate a sample material (col. 8:3-6); however, there is not at least one compartment connection structure in contact with the outer radius of the unvented channel. Each end of the channel directly contacts a compartment (60, 62). Also, the channel is preferably vented (col. 9:9-13).

b) Claims 2-34 and 42 depend directly or indirectly from allowable claim 1.

c) Claim 37: the combination of limitations requires the compartment connection structures to be in contact with the outer radius of the unvented channel and the step of "rotating the device to cause the solutions to move from the unvented channel to the plurality of compartment connection structures." In Bedingham et al. (US 6,662,830 B2) the compartment connection structures (30c, 63) are not in contact with channel 50, which may be unvented, but with the compartments (20d, 60) at the ends of the channels. See Figure 1. Furthermore, the compartments and compartment channels are arranged so that when the device is rotated solutions move from the compartment connection structures toward the channel, not from the channel to the compartment connection structures. See co. 5:10-23; col. 5:32-42; col. 8:14-29; and col. 12:14-26. Also Bedingham et al. does not disclose performing iso-electric focusing.

d) Claims 38-41 depend directly or indirectly from allowable claim 37.

e) Claim 43: the combination of limitations requires the step of "applying a centrifugal force to the solution, thereby fractionating said solution."

Bedingham et al. (US 6,662,830 B2) does not apply a centrifugal force to thereby fractionate the sample. The centrifugal force is applied to process the sample and to load the sample and electrophoresis medium into the channel. See the abstract; col. 9:27-62; col. 2:58 – col. 3:6; col. 5:3-23; col. 5:31-42; col. 12:14-26; and col. 12:47-51. In Bedingham et al. the sample is fractionated by electrophoresis and optionally beforehand with a filter. See col. 1:65 – col. 2:2; col. 12:14-26; col. 13:66 – col. 14:13; and col. 14:4-26.

f) Claim 44 depends from allowable claim 43.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
September 20, 2006